

### **REMARKS**

Claims 160-163 and 165-166 are pending. Claims 167-200 have been withdrawn as directed to a non-elected species. Claims 160-163 and 165-166 stand rejected. Claim 160 is amended to more particularly point out and distinctly claim the invention. In particular, claim 160 is amended to replace the phrase “recrystallization of” with the term “renaturing.” Moreover, the group reacting with the insertion compound is corrected to now read “amines.”

Support for the amendment is found in the specification as originally filed, e.g. at p. 9, ll. 4-, which discloses features of the chemical moiety that can be attached to the denatured nucleic acid. In particular, the chemical moiety can include “an acid group,” which “can react with amine groups of the bases, to inhibit the DNA from recrystallizing or renaturing.” *Id.*

#### **Item 1**

Applicant thanks the Examiner for the entry of the Amendment filed on June 13, 2007, and the information disclosure statement filed on December 7, 2006.

#### **Items 3. Rejections under 35 U.S.C. §102(e)**

Applicant respectfully notes that the rejection of claims 160-163 and 165 under 35 U.S.C. 102(e) over U.S. Patent 6,017,696 is withdrawn.

#### **Item 5. Rejection under 35 U.S.C. 103(a)**

Applicant also respectfully notes the withdrawal of the rejection under 103.

#### **Item 6. New Rejection under 35 U.S.C. 112 – Second Paragraph.**

Claims 160-163, 165 and 166 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for use of the phrase “prohibits recrystallization of said denatured segment” of a nucleic acid.

The Office Action suggests that the phrase is insolubly ambiguous.

Applicant respectfully asserts that the phrase is unambiguous when properly read in the context of the specification.

In the context of the patent specification, the term *recrystallization* is merely used as a substitute for renaturing. In this regard, denaturation of duplex nucleic acids is also termed melting and the reverse of melting is *recrystallization*. The references that Examiner has cited appear, however, to use *recrystallization* to depict formation of long-range three-dimensional organizations of molecules. By contrast, the application is self-consistent and uses the term to depict a first order phase transition, i.e. renaturing.

The rejection is mooted by the amendment of claim 160, which now claims “renaturing said denatured segment.” Claims 161-163 and 165-166 incorporate all the limitations of claim 160 from which they depend.

Consequently, Applicant respectfully requests withdrawal of the rejection.

Item 8. New Rejection under 35 U.S.C. 112 – Enablement.

Claims 160-163, 165, and 166 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Office Action indicates that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. “Particularly difficult is determining whether the compound would function to ‘prohibits *recrystallization* of the denatured segment.’ DNA crystallization, as discussed by Osica et al. ... required particular conditions that are fairly extreme.” Office Action at p. 5.

The specification and claims do not use the term *recrystallization* in the same way as Osica et al. do.

It is a tenet of patent law and practice that an inventor can be his own lexicographer.

Despite this practice, and solely to advance prosecution of the application to early allowance, the claim has been amended to recite *renaturing*. It is believed that the amended claim more particularly points out the invention to which the inventor is entitled.

The Office Action discusses the factors from *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) as indices of whether a disclosure is enabling. In view of the amendment of claim 160, these factors are believed moot. Nevertheless, in order to be fully responsive, we address each issue raised in the Office Action.

#### The nature of the invention

The Office Action characterizes the invention as being in the chemical and biological arts.

The invention as claimed is more particularly a method of storing information that merely uses chemical derivatives of nucleic acids as markers of the information. A novel internal combustion engine uses chemical reactions, yet would be a mechanical invention. Similarly, the instant invention is reasonably placed in the field of information science.

#### The breadth of the claims

After entry of the amendment, the claims would be limited to insertion compounds that react with an amine group and prohibit renaturation of the nucleic acid. The specification identifies carboxylic acids, acid chlorides, isocyanates, and phosphonic dichloride as useful reactive groups. Applicant respectfully asserts that one of skill in the art would readily identify the range of insertion groups that would react with amine groups of nucleic acids. Moreover, the process of renaturation of a nucleic acid is sufficiently understood within the art.

Thus, the breadth of the claim to a method of storing information in a biological molecule is substantially limited by the elements of the claim as understood in the context of the specification.

### Quantity of Experimentation

The Office Action points particularly to a difficulty in determining whether the insertion compound would function to prohibit *recrystallization* of the denatured segment, as DNA crystallization would be understood in view of Osica et al. The claim has been amended to obviate this issue.

Renaturation of a nucleic acid is a relatively routine measurement in the art, and not undue.

### The unpredictability of the art and the state of the prior art

With regard to this criterion, the Office Action focuses on preventing DNA *recrystallization* and the conditions necessary for formation of 3-dimensional long range crystal organizations of DNA according to Monar et al. Indeed, “it is entirely unpredictable how to prevent recrystallization when there is little likelihood that crystals will form.” Office Action at p. 6.

By contrast to the meaning of *recrystallization* used in the Office Action, *renaturation* of nucleic acids, as used in the amended claim, has been very intensively studied since the seminal work of Watson and Crick. The resulting vast body of literature would guide the user in the use of the invention.

Thus, in this understanding, the state of the prior art supports enablement of the invention as claimed.

### Working Examples

The specification has detailed descriptions of the invention of the instant claims, including text at pages 10-14 disclosing chemistry of insertion compounds and at pages 25-26 disclosing use of the invention as a bar code. The presence or absence of working examples is not determinative by itself.

### Guidance in the Specification

The Office Action indicates that the specification never tells the ordinary practitioner what is meant by “prohibiting recrystallization” or what phase of nucleic acid is meant by this phrase. Further, the specification fails to teach how reaction with an *amide* group will prohibit recrystallization.

Applicant respectfully submits that the specification does not differentiate between renaturation and recrystallization, and uses the terms interchangeably to mean formation of a duplex nucleic acid. Figure 5 illustrates the reaction of monovalent and bivalent insertion compounds with a denatured portion of duplex nucleic acid to prevent, or partially prevent, renaturation. One of ordinary skill in the art, upon reviewing Figure 5 in view of the specification, would readily recognize that covalent attachment of an insertion compound to the *amines* of adenosine, guanosine, or cytidine residues would interfere with the normal Watson-Crick base coupling depicted in Figure 5.

### Level of Skill in the Art

Applicant does not dispute that the level of skill in the art is at least moderately high.

On the basis of the above comments, Applicant respectfully asserts that one of skill in the art would be able to practice the invention upon reading the specification and reviewing the figures.

Moreover, the claims as amended are believed to be patentable in view of the prior art of record.

In view of all the above remarks, withdrawal of all rejections is respectfully requested.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicants believe no additional fees are due with this amendment. However, if any additional fees are due, please charge our Deposit Account No. 22-0185, under Order No. 20140-00288-US1 from which the undersigned is authorized to draw.

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Respectfully submitted,

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